

510(K) Summary of Safety and Effectiveness

FEB - 8 2001

K003641

- (1) **Submitter's name:** Biocomposites Ltd
Submitter's address: Etruscan Street, Etruria, Stoke-on-Trent, ST1 5PQ, England
Submitter's telephone number: 44 (0) 1782 206500
Contact person: Stephen Bratt
Date summary prepared: 22 November 2000
- (2) **Trade or proprietary device name:** Biosteon™ Screw
Common or usual name: Bone Fixation Screw
Classification name: Class II
- (3) **Legally marketed predicate device:** Bio Interference Screw (Arthrex)
BioScrew (Livatec)
BioLok® Screw (Biocomposites)
- (4) **Subject device description:**
The Biosteon™ Screw is a cannulated, sterile, single-use bone screw made of an absorbable polymer similar to that used in bioabsorbable suture and will gradually be absorbed into the body. The Biosteon™ Screw is manufactured from a mixture of Hydroxyapatite (HA) and poly (L-lactide) (PLLA).
- (5) **Subject device intended use:**
The Biosteon™ Screw is indicated for use in anterior cruciate ligament (ACL) reconstruction procedures where the surgeon:
- places the graft in tibial and/or femoral tunnels; and
 - inserts screws between the tunnel wall and graft to hold the graft in place.
- The Biosteon™ Screw is used to provide interference fixation of patellar bone-tendon-bone grafts in ACL reconstruction.
- The Biosteon™ Screw is used to provide interference fixation during femoral and/or tibial fixation in ACL reconstruction using a soft tissue graft (semi-tendonosis gracilis).
- (6) **Technological characteristics:**
The Biosteon™ Screw has the same technological characteristics (i.e., design and material) when compared to the predicate devices.
- (7) **Performance data:**
Test results confirm that this composite has the requisite strength to provide early and sustained fixation of the graft. Pull out test results compare favourably with the predicate devices.
- (8) **Basis for substantial equivalence:**
The Biosteon™ Screw is equivalent in design, materials and indications to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. J. Stephen Bratt
Managing Director
Biocomposites Ltd.
Etruscan Street, Etruria
Stoke-on-Trent
Staffordshire, ST1 5PQ
United Kingdom

Re: K003641
Trade Name: Biosteon™ Screw
Regulatory Class: II
Product Code: HWC
Dated: November 22, 2000
Received: November 27, 2000

Dear Mr. Bratt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

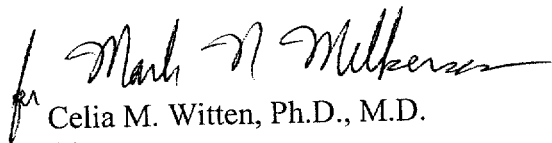
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

Page 2 - Mr. J. Stephen Bratt

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

K003641

Biosteon™ Screw

Indications For Use

The Biosteon™ Screw is indicated for use in anterior cruciate ligament (ACL) reconstruction procedures where the surgeon:

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- inserts screws between the tunnel wall and graft to hold the graft in place.

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for Mark N. Melker

(Division Sign-Off)

Division of General, Restorative
and Neurological Devices

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